ALVAREZ & MARSAL
HEALTHCARE INDUSTRY GROUP

Report of the Independent Consultative Expert (ICE)

Evaluation of Quality Assessment and Performance Improvement (QAPI) Program

for

Parkland Health & Hospital System

Dallas, Texas

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Submitted To:

Centers for Medicare and Medicaid Services and **Parkland Health & Hospital System**

Submitted By:

Alvarez & Marsal Healthcare Industry Group, LLC
Columbia Square
555 Thirteenth Street, NW, 5th Floor West
Washington, DC 20004
+1 202 729 2100

Evaluation of Quality Assessment and Performance Improvement (QAPI) Program at Parkland Health & Hospital System

Introduction and Overview

As part of the engagement under the Systems Improvement Agreement (SIA) between Parkland Health & Hospital System (Parkland or Hospital) and the Centers for Medicare and Medicaid Services (CMS), Alvarez & Marsal Healthcare Industry Group, LLC (A&M, ICE Team, we or us) was asked to conduct an analysis of the Hospital's current Quality Assessment and Performance Improvement (QAPI) program. The purpose of the QAPI analysis is to evaluate the Hospital's current QAPI program in terms of its ability to meet the requirements of 42 C.F.R § 482.21 for an effective, hospital-wide, data-driven QAPI program that is used to develop and implement performance improvement activities and projects that improve the quality of care and the safety of patients at Parkland. This QAPI analysis includes an evaluation of the adequacy of Parkland's QAPI resources, the qualifications of the QAPI staff, and the level of engagement of the Parkland governing body, administrative officials and medical staff in the QAPI program.

Parkland's QAPI program has not set the expectations for the organization to be proactive in improving the Hospital's overall performance and to focus on the delivery of safe patient care. It does not capture all quality related issues, events and initiatives and does not adequately prioritize and appropriately deploy resources as needed. The program does not engage in enough data analysis or trending studies, or share information gleaned from that data across the organization. The Parkland QAPI program often views quality through the lens of reported "adverse events." But too often adverse events are viewed as isolated incidents as Parkland, rather than symptoms of a systemic problem within the organization.

Organization wide, Parkland's QAPI program does not effectively integrate into each Hospital department and unit. As noted throughout our Gap Analysis report (Report of the Independent Consultative Expert to CMS and Parkland dated February 2, 2012), few if any, Hospital departments have department-specific QAPI plans, as required by the Medicare Conditions of Participation.

Even within the Quality of Care Department (Quality Department or Department), which is responsible for Parkland's QAPI program, there is a high degree of siloing as units within the Quality Department do not interact effectively and share information with one another. Recent organization changes in the Quality Department to fold together the Performance Improvement group and Continual Readiness group -- the group that assists the Hospital in understanding Medicare and Joint Commission standards and policies -- have already begun to improve the Hospital's effectiveness in responding to state and federal surveyors and investigating adverse patient events.

Parkland's QAPI program, as currently organized, is also limited with respect to its collaboration with other organization-wide functions that should also be focused on care quality such as the Compliance, Internal Audit and Legal departments. Recently the Interim Chief Executive Officer (CEO) launched a project to better align the work of these four key departments: Quality, Compliance, Internal Audit and Legal. Better alignment of those four functions will be part of the QAPI improvement process.

Finally, because of the belief that "quality" is a department or building at Parkland, rather than a cultural trait, Parkland's senior leaders need to convey a consistent message throughout the organization on the purpose of QAPI and how each employee must own the quality of all of the work they perform as well as the work of their colleagues.

Medicare Conditions of Participation (CoP) Requirements for QAPI

CMS expects hospitals to have a fully-functioning QAPI program to serve a "self-policing" and "self-improvement" role for patient protection and regulatory compliance. The program should be hospital-wide, data-driven, and designed to increase patient safety and continually improve the quality of care provided within the organization. 42 C.F.R § 482.21

The hospital's governing body, in this case the Parkland Board of Managers (BOM), must also ensure that the QAPI program reflects the complexity of the hospital's organization and services, that it involves all hospital departments and services (including services under contract or arrangement) and that the program focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

A hospital's QAPI program must meet the following parameters, in order to be compliant with the Medicare CoP:

- ***Scope of QAPI Program:*** Must include an ongoing program that shows measurable improvement in evidence-based indicators that will improve health outcomes and identify and reduce medical errors. The QAPI must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.
- ***QAPI Data:*** Must incorporate quality indicator data including patient care data and must use the data collected to:(i) monitor the effectiveness and safety of services and quality of care; and (ii) identify opportunities for improvement and changes that will lead to improvement. Frequency and detail of data collection must be specified by the hospital's governing body.
- ***QAPI Activities:*** Must set priorities for QAPI performance improvement activities that: (i) focus on high-risk, high-volume, or problem-prone areas; (ii) considers the incidence, prevalence, and severity of problems in those areas; and (iii) affect health outcomes, patient

safety, and quality of care. QAPI program performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. A hospital must take actions aimed at performance improvement and, after implementing those actions the hospital must measure its success, and track performance to ensure that improvements are sustained.

- ***QAPI Performance Improvement Projects:*** As part of its QAPI program, a hospital must conduct performance improvement projects. The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations. One of the projects may include developing an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes. The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects. Hospitals are not required to participate in a QIO (Quality Improvement Organization) cooperative project, but its own projects are required to be of comparable effort.
- ***Executive Ownership of QAPI:*** The hospital's governing body must ensure that: 1) a QAPI program is established and maintained; 2) the hospital's priorities for improved quality of care and patient safety are met; 3) clear safety expectations are established; and 4) adequate resources are allocated to the QAPI.

Methods to Review Parkland's QAPI

In order to evaluate the QAPI program at Parkland, A&M conducted interviews with the head of the Department and all direct reports. We also met with: a variety of senior and mid-level hospital administrators and department heads and leaders; members of the Parkland Board of Managers; and the Hospital's Medical Staff Office support staff and Medical Staff leadership. We also attended various committee meetings including: Quality of Care Committee, Board of Managers Quality Committee, weekly Patient Safety huddles, Root Cause Analysis (RCA) meetings, Medical Executive Committee, PCRC (Patient Care Review Committee) meetings and planning meetings. We also reviewed a variety of documents including: QAPI plans, reports to Board of Managers and committees, PSN (Patient Safety Network) reports, RCA reports, peer review committee records, credentialing files (samples), performance improvement plans, reports and plans of corrections to State and CMS and medical records and case management plans within Parkland's Epic Electronic Medical Records (EMR) system.

A fully functioning QAPI program should include a "self-policing" mechanism that detects areas in need of improvement and proactively investigates areas for potential needs for improvement. This activity would include the human resource activities of hiring of personnel and credentialing and privileging of the medical staff. It would also include regulatory readiness for both the accrediting body and CMS. Investigation and analysis of data are critical to this component. A fully functioning QAPI program should also include the "Self-Improvement" and "Prevention" component. This includes the functions of auditing, testing, and peer review.

Hospitals must work to guarantee not only a safe patient experience, but a care experience that is also cost efficient and consistent with best practices. Through the ICE survey and interview process a number of trends emerged related to how quality is viewed at Parkland. "Quality" at Parkland is often viewed as a "Department" or "Building" -- Support Building B in this case where the Department is housed -- which is responsible for "quality" rather than quality being an institutional and cultural trait as well as a imperative for all staff and employees. The primary challenge for Parkland, even before addressing Quality program issues, is to inculcate a sense that quality belongs to everyone.

Leaders set the tone for the organization's QAPI efforts. They need to be totally committed not only to understanding rules and regulations but to enforcing the "spirit" of the regulations as well. Quality needs a consistent message throughout the organization on its purpose and how each employee should engage and own quality.

There are several overall issues and concerns with the current state of the QAPI program at Parkland. While the current QAPI plan on paper attempts to mirror the Medicare Conditions of Participation (COP) requirements, the actual practice and execution does not conform to the COP requirements. The QAPI plan does not comply with Joint Commission requirements and related/cross walked CoP. Where they exist, departmental QAPI programs are not comprehensive, systematic, and are not fully integrated into the house-wide QAPI program. Many QAPI indicators collected are not department or unit specific and may not be relevant to patient populations served. In addition, for those patient care services provided under contractual agreements, the quality monitoring of those services is incomplete and does not provide for Medical Staff input and recommendations regarding the retention of the services.

Parkland must begin its QAPI corrective action activities by revising its current QAPI Plan. The QAPI plan needs to include all the CMS required elements, ensure that the plan and departmental indicators are appropriately tailored and customized to reflect the various departments and the populations they serve. The plan must outline the methods to capture data needed to improve care and outcomes and improve patient safety. The plan should be re-written an approved by the Parkland BOM Quality Committee no later than March 31, 2012.

Quality Issue Detection and Data Analysis

Currently at Parkland, potential quality issues are brought to the attention of the organization and specifically the Quality Department through the Patient Safety Network (PSN) reports, direct referrals and some limited results from the UHC comparative database. This funnel of information is not sufficient to uncover all potential quality issues. During our review of Parkland's QAPI program, we did not find evidence that the Hospital regularly used other techniques to uncover potential quality concerns such as through: regular rounding and mock surveys, patient complaints, daily huddles, Joint Commission safety alerts, departmental meetings or graduate medical education audits. We did not see evidence of the Epic database being used on an organized and systemic basis to glean practice pattern information. We only saw limited use of external databases but did not see use of information from groups such as the American College of Cardiology, Vermont Oxford, and other professional organizations. We did not observe any concurrent referrals to the Quality Department based on objective indicators and severity and clinically adjusted comparative databases such as the Delta Group database. In short, there is a limited source of information – in this case PSN safety reports – that are generated based on an individual's judgment and then funneled to the Quality Department to perform its QAPI function. This is in contrast to an effective QAPI department, which would expand and centralize its quality data collection to ensure that the organization is capturing all issues, events, trends and initiatives.

While there is an abundance of potential quality data at Parkland, we did not observe significant analysis of the data. In addition to collecting data to submit "core measures" reports to CMS, the Clinical Information Services (CIS) group runs monthly reports for a number of clinical conditions and events, such as:

- Central line infections
- Urethral catheter device days
- Blood utilization
- Medication administration within 30 minutes of schedule
- Pain assessments
- Psychiatric consults
- Restraints
- Wound care
- Critical laboratory results.

We did not see evidence of how this data was analyzed or reported up to the Quality of Care Committee or the BOM Quality Committee, or how individuals within the Hospital utilized this data to reduce, for example, central line infections or the use of restraints.

As we noted in the Gap Analysis report, Parkland utilizes a significant number of patient restraints relative to its population. Our own review of the daily restraint log for a six-week period of time (2 – 3 days per week) indicated an average of 60-70 Parkland patients are in restraints each day. Utilizing 65 patients as an average, this equates to 10% of the entire hospital census and 17% if WISH census is removed. An article in The Journal of Nursing Scholarship, 2007, 39(1)30-7, identified a use rate 50 episodes per 1000 patient days or 5%, in a review of 40 acute care facilities. Utilizing this study, Parkland's rate is twice the expected rate. During our review of the QAPI program, we did not find, for example, reports analyzing Parkland's use of restraints, comparison of restraint use to other hospitals or projects to reduce use of restraints. We also did not see studies or reports done by the Department regarding injuries or medical complications to a patient that might be attributed to the use of a restraint.

In terms of quality reporting to the BOM, much of the recent data presented to the BOM Quality Committee has either been in raw form – e.g., descriptions of significant patient care events, which may qualify at "sentinel events" or mandatory reporting events – or in a format where context is not given to certain data. For example, the BOM Quality Committee received what was labeled as 12 month trending data for:

- Serious Event Rate
- Adverse Event Rate
- Serious Reportable Events
- Patient Safety Indicator Composite, and
- Hospital Acquired Infections.

The materials suggested that the Hospital's trending data was compared to some external benchmarks such as the National Quality Form, or the federal Agency for Healthcare Research & Quality (AHRQ). However, there was no explanation of how the Hospital selected the "control limits" or comparators. Nor was there explanation of how data was collected and what the trending data meant, if it could be understood.

The BOM Quality Committee would have been better informed with an easily understood report on, for example, the top 20 safety errors by type, trended for 12 months (or longer), with an explanation of efforts underway to reduce that specific type of safety error. For safety errors that resulted in significant harm to patients, such as death or loss of function or permanent or serious harm, similar trending data should also be presented, along with information on QAPI initiatives to reduce or prevent such events in the future. And for all of the safety events reported, there should be some comparative data presented, such as how Parkland rates in comparison to the number of such events by patient days or some other metric. The external benchmarks are useful and essential, but only if Parkland's performance is clearly understood next to those national statistics.

In order for a QAPI program to be effective, a hospital must decide what data to collect and how to analyze that data. While general clinical data collection should be performed and that data analyzed to spot trends, ongoing data collection and analysis should be related to identified risks within the Hospital. In Parkland's case those risks might include: medication errors, delays in care, patients leaving against medical advice or eloping or diagnostic tests not being performed in a timely manner. Again, we did not see many regular trending reports focusing on Parkland-specific safety issues. Recently, the Quality Department has been presenting additional data on medication errors

Useful or meaningful information is not always derived from the data and therefore cannot be routinely presented. Our review did not detect a formal process for getting reports produced or an orderly and routine analysis of reports that are generated. Compliance with Medicare CoP requires that real data, properly distilled and delivered in a timely manner, needs to drive performance improvement. It must be accurately collected, analyzed against the elements for which it was collected and trended. Data must identify or negate that a problem exists and corrective action. Data must then be utilized to evaluate that corrective action was effective.

Because Parkland does not have a robust, central "funnel" to capture all QAPI related issues, the QAPI program does not have a clear prioritization of efforts and resources. Further, we did not see clear evidence that improvement efforts are evaluated and that the results of improvement efforts are clearly reported through the Quality of Care Committee (QCC), the Hospital's Medical Executive Committee and subsequently to the Quality Committee of the BOM.

Identification and investigation of patient safety issues at Parkland are not consistent and timely. Sentinel events and near misses are not always identified as such by the Parkland QAPI program. Root Cause Analysis (RCA) most often starts from the receipt of a PSN report. When conducted, RCAs are often conducted in a vacuum and are not consistently analyzed for trends. Frequently they are not conducted or completed in a timely manner to adequately address the quality concern. Parkland's use of the RCA process tends to be a discussion of the event in question and does not always focus on system issues or processes. Many of the RCA sessions we observed happened many days, if not several weeks, after the adverse event giving rise to the RCA. Delays in conducting RCAs result in fact gathering errors as immediate memories of facts fade. And delayed RCAs mean that unsafe practices may be continuing, putting patients at risk. We observed that RCA measurement at Parkland is reactive and follow-up is not consistent.

Parkland's QAPI program, as currently organized, is also limited with respect to its collaboration with other organization-wide functions that should also be focused on care quality such as the Compliance, Internal Audit and Legal departments. From our observation, the Compliance Department is only infrequently invited to assist in quality investigations. This is different than many medical organizations where the Compliance Department is involved in significant safety and care investigations given that the Compliance Department (and often Internal Audit) often

has investigatory resources to bring to bear to investigations. Recently the Interim CEO launched a project to better align the work of these four key departments: Quality, Compliance, Internal Audit and Legal. Better alignment of those four functions will be part of the QAPI improvement process and will increase information on potential quality of care events and trends going to the Quality Department.

Overall, the Parkland's current QAPI program does not reflect or adequately address the complexity of the organization and the services provided. It is not gathering quality information and data from multiple sources within the organization and continually comparing the organization to outside benchmarks. It does not involve all Hospital departments and services (including those services furnished under contract or arrangement). It does not consistently focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. §482.21 Condition of Participation: Quality Assessment and Performance Improvement Program. Tag A-0263

Quality Department - Organization and Structure

The Quality Department is currently composed of five groups: Patient Safety, Utilization Management, Performance Improvement, Infection Prevention and Clinical Information Services. Utilization Management and Infection Prevention were previously evaluated in the Gap Analysis report. Until December, the Department also had a Continual Readiness group, which took the lead in preparing Hospital staff for CMS and Joint Commission surveys. That group was recently folded into the Performance Improvement group.

The Department currently has over 60 FTEs. The Quality of Care Department is more than adequately resourced with personnel. However, position descriptions, requirements and expectations should be clearly outlined and relayed to the staff. The Action Plan recommends certain realignment and reorganization of the Quality Department function to acquire the skills needed to implement a house-wide QAPI program that will meet regulatory requirements.

The Department currently reports to a Senior Vice President/Chief Quality Officer (CQO), who is a physician. In turn the CQO reports to the Hospital's Chief Medical Officer (CMO). The CMO reports to the Hospital Chief Executive Officer (CEO). The CMO and CQO also report on a regular basis to the Quality Committee of the Hospital's Board of Managers (BOM). The BOM is the Hospital's governing body. The Quality Committee of the BOM is ultimately responsible for the Hospital's QAPI program.

The CQO also chairs the Hospital's Quality of Care Committee (QCC), which consists of members of the Medical Staff and Hospital administration.

The Parkland Quality Department itself is operating in a siloed environment. Groups within the Quality Department do not interact effectively with one another. Our interviews and interactions with the groups suggested a culture of "secrecy" among the sections. These walls must disappear if the Parkland QAPI program is to be successful. In addition, the Parkland Quality Department needs more integration and teamwork with Compliance, Internal Audit and Legal as well as the Compliance Department should be more involved in quality assessment and assurance activities. Please refer to the Governance section of the Corrective Action Plan for recommendations for these structural changes.

Continual Readiness

A "Continual Readiness" group was established in the Quality Department to ensure that the organization was ready for any regulatory survey and to prepare the plans of correction when needed after regulatory surveys. The Continual Readiness group has struggled preparing Hospital departments for surveys. And the plans of correction drafted and submitted by the Continual Readiness group have not all been accepted by regulators and even where accepted have not led to sustained correction of issues cited by regulators and surveyors. In December, the head of the Continual Readiness group retired from the organization and the Continual Readiness group was folded into the Performance Improvement (PI) section, which took over these functions. This is an appropriate change as Continual Readiness for CMS and Joint Commission surveys should be an integral part of the PI section, not a separate section.

Continual Readiness used to utilize tracer methodology as their evaluation tool and every department was assigned a consultant from the section. In 2010, however, the Continual Readiness group stopped using tracer methodology and only recently re-instituted it. Without tracer methodology, the Continual Readiness group will not be able to uncover fully issues in quality of care.

In order to better utilize the resources available, baseline data derived from surveys and an initial set of tracers should be utilized to prioritize the patient tracer program. Staff should serve as consultants to the departments to effect corrective actions and evaluate the effectiveness of the interventions. The baseline data from an initial set of tracers should be completed and analyzed by March 30, 2012. Corrective action plans should be developed by April 15, 2012 and implementation initiated by April 30, 2012.

Performance Improvement (PI)

The historical Performance Improvement function at Parkland has been limited both in scope and results. The Quality Department recently hired a new head of PI, who is engaged in an effort to more systemically decide when to establish a performance improvement program for a particular issue or problem. The new head of PI is also working to assist all Hospital departments in establishing their own, department-specific QAPI programs.

In our survey, we only found one department, Women and Infants Specialty Health (WISH) services, to have a department-specific performance improvement (PI) plan. The Medical/Surgical division PI plan, for example, looks at global indicators such as falls and medication errors as opposed to population specific indicators. Where departments have the start of a department PI plan, they are reporting up through multiple different channels such as Blood Utilization, Radiation Safety, and Pharmacy and Therapeutics. However, these results do not reach the QCC, Medical Executive or Quality Committee of the Board.

In order to be compliant with the Medicare CoP, every Parkland department should have a departmental-level PI Plan with indicators that are appropriate for the patient population served or the services provided. This PI plan must include the quality monitoring of all patient services provided by contract. The plan and proposed indicators need to go to the Quality of Care Committee (QCC) and ultimately be reviewed by the Quality Committee of the BOM. The BOM Quality Committee global goals can then be incorporated into the goals of the individual departments. The Performance Improvement group should identify, in the QAPI Plan, a regular reporting schedule for each department. Reporting at least four times per year should be required with additional reporting requirements if the department is not meeting specific quality targets.

If a department routinely reports to another committee, it should also funnel that PI information to the QCC (e.g., Pharmacy, Lab). House-wide committees also need to funnel information to the QCC (e.g., Safety, Disaster Preparedness, etc.)

Within the Performance Improvement group in the Quality Department there has historically been little coordination of new and existing projects. Today, some go through QCC while others go directly to the Board Quality Committee. While project proposals and charters are routinely submitted through QCC, there is not a formal process in place to prioritize projects. As a result, fiscal and human resources are not well coordinated and the governing body is not well informed. All requests for PI Projects should be taken through the QCC. A formal request for the project should be filled out by the requesting area and the QCC should approve or decline the request based on organizational priorities. These should then go to the Quality Committee of the BOM for final approval and allocation of resources. The PI group leader has recently started efforts to centralize the approval process for new PI projects and centralize reporting obligations, by requiring all new department PI projects to be reviewed and approved by the QCC.

We did not find that PI projects are routinely monitored to evaluate if they achieved the goals and outcomes for which they were designed and they are not routinely re-evaluated to see if the changes remained effective. In order to be in compliance with the CoP, Parkland should use the QCC as a "net" to capture all PI projects house-wide.

As part of the ICE Action Plan, we recommend that each Parkland department should have a departmental-level PI, with indicators that are appropriate for the patient population served or the services provided, in place and approved by the QCC no later than April 30, 2012. Subsequently indicators should be submitted annually to QCC for approval. Each department should then report to the QCC on at least a quarterly basis based on the reporting schedule. This should commence in April 2012 for all departments who have not reported to the QCC in the last 6 months

Departments that are within 5% of the established threshold for their PI plan would not have to be physically present to report their results to the QCC. Departments that are more than 5% off target should need to be physically present at the QCC to outline their plan for improvement. Departments that are more than 10% off target should report monthly to the QCC until they are within 5% of the target.

Departments with outsourced or contracted patient care services arrangements should report quarterly to the QCC on the contract service and report recommendations for retention according to the renewal schedule. As part of the ICE Action Plan, we recommend that the QCC in conjunction with Parkland's Contract Management Unit, create a data base of all contracted patient service arrangements, as well as key contracts directly affecting patients, like environmental services (EVS), in order to track the agreements and the responsibility of the relevant department to continuously evaluate the quality of services delivered under the contract according to the contract terms and Parkland's QAPI program. Additionally, as part of the Organization, Governance and Leadership section of the Action Plan, we recommended that the Board of Managers Quality Committee dovetail with the QCC on the outsourced contract quality review function and periodically review key outsourced patient care related contracts and review quality scores for those vendors. (Action Plan, Section 2.01.)

Departments that report to other committees should funnel their PI information to the QCC (e.g., Pharmacy, Lab) starting no later than April 30, 2012. House-wide committees should start reporting through the QCC in April 2012 as well.

The PI reporting structure should be as paperless as possible, utilizing the existing secured and shared drive. QCC committee members would be responsible for viewing the materials for the meeting in advance. This will allow the meeting to concentrate on areas in need of discussion.

All requests for PI Projects should be taken through the QCC starting in April 2012. A formal request for the project should be filled out by the requesting area. The QCC should approve or

decline the request based on organizational priorities. A formal charter, with restrictions outlined and reporting requirements defined, should be recommended by the QCC and awarded by the Board Quality Committee.

Parkland has allocated sufficient resources to the QAPI program. However, without coordination and prioritization of efforts, these resources may not be utilized to the organization's best benefit.

Patient Safety

The Patient Safety group of the Quality Department processes and investigates patient safety and adverse care events. It maintains the Hospital's safety reporting system through the UHC Patient Safety Network (PSN) and reviews and acts on reports generated by PSN. The Patient Safety Group facilitates the Hospital's Root Cause Analysis process and also performs many of the investigational, triaging and initial review components of the Medical Staff Peer Review process.

The fundamental role of a patient safety reporting system is to improve the hospital's overall delivery of patient care. Patient safety reporting must be straightforward, non-retaliatory and uncomplicated in order to encourage all staff to report trigger events. All safety reports should be analyzed by a common systematic method that includes feedback of the findings. Analysis and trending of the safety event data should be used in order to recommend changes in processes and systems to improve patient safety.

Currently, the Parkland Patient Safety group is highly reliant on the PSN reporting mechanism in order to capture adverse patient care events. In addition to this resource, they should glean potential safety issues from other methods as well such as: patient floor and care area rounding, direct reporting, patient complaints, and daily huddles as well as other sources that indicate potential trends (comparative databases, committee reports, etc.)

The current safety reporting process is outlined in Parkland's *Administrative Procedure; Section Legal Affairs: Admin 5-18; RD 8-11*. The current procedure outlines the immediate action that should be taken by all Parkland employees following an adverse event to a patient or visitor. The first step requires that a Patient Safety Net (PSN) report be competed in a timely manner by an employee or physician. These reports are submitted to PSN electronically by the reporting employee or physician.

Parkland's current safety reporting procedure does not describe the method by which patient events that do not qualify as Joint Commission "sentinel" events or National Quality Forum (NQF) safety events are to be investigated. The current procedure standard states that: "after consideration of the extent of harm, severity and likelihood of recurrences it will be determined if the extent and degree of an institutional led investigation will occur following the adverse

event." This current standard allows human judgment in determining the depth of the investigation or if an investigation will occur. Parkland should establish clear standards on what events will be investigated, in addition to sentinel events, NQF events and mandatory state reporting events.

During the survey process we observed several safety events that triggered a PSN report that did not trigger a hospital investigation, or a robust investigation. We intervened on several safety reports, and raised our concerns to the Hospital's senior leadership in some cases, strongly recommending that a second review occur or that additional evidence should be considered. One such event involved the death of a patient following the administration of a narcotic drug by a nurse, where there was no written or verbal order by a physician to administer the drug. In that case the original investigation did not uncover the fact that the nurse administered drugs without a physician order.

It also appears that once a PSN report is submitted it can be altered or deleted by the staff in the Patient Safety Department. Often more than one safety report is submitted by different employees or physicians on a single patient event. In such cases, Patient Safety staff may delete some of the duplicate reports. This practice has caused discrepancies and vital information has been lost before an investigation has been completed. In our Action Plan we recommend that a feature be added to the PSN reporting system to prevent any reports from being deleted, even if those reports are duplicate reports of the same safety event.

Our review of adverse event investigations at Parkland suggested that adverse events are too often viewed as isolated incidents, rather than symptoms of a systemic problem. Trending is not an active process, but a perfunctory process. Data is entered but not evaluated during the input process.

With respect to triaging safety reports and adverse events, Patient Safety staff is often not aware of what events to escalate or investigate. Often, there is little investigation of adverse events other than chart review, if that is performed. Interviews are only conducted on what are believed to be more significant cases. Frequently the answers to a potential quality issue cannot be found in the medical chart alone. The Patient Safety should investigate thoroughly any potential quality issues before ratings are assigned and the PSN closed out. The staff needs to sift and distill the PSN or other report or allegation source to answer: "*What does this mean? What really happened and why? Is this a one-time event or a trend? What should we do to make sure it does not happen again?"*

The Root Cause Analysis (RCA) process is directed by the Patient Safety group. RCAs are not currently being conducted according to Parkland's own policy and procedures. RCA's are supposed to begin within 24 hours of the incident. Many of the RCAs that we attended during our survey period were conducted days, if not weeks, after the incident. It is extremely difficult

to remember details with this protracted timeframe. RCAs, similar to PSNs, are too often viewed as discrete events by the Parkland Quality Department. When performing RCAs or investigating PSNs, Patient Safety staff needs to ensure that any relevant trends are also identified.

RCAs are facilitated by a member of the Patient Safety staff. Information gathering, including an analysis of any previous occurrences, prior to the initial meeting is often lacking. A & M observations of the actual process have included that RCA group facilitation skills need improvement, knowledge of the process and definitions needs improvement, and knowledge of appropriate interventions needs improvement. The process would also benefit by implementing strategies based on the information from the RCA to help reduce the future risks of similar events.

Clinical Information Services (CIS)

This group in the Quality Department prepares both regular and ad hoc reports as requested by the Parkland organization (90%) and University of Texas Southwestern Medical Center (UTSW) physicians who are performing research (10%). Few of the departments in the Hospital, including the other sections in the Quality Department, know how to pull reports out of the various data bases and systems and very few Hospital departments do this as part of their regular functions.

The CIS group also submits certain required reports to the State of Texas and maintains the database for the Rapid Assessment Team. CIS acts as the interface with the Medical Information Management Department (research) on EMR system architecture but not on analytics. CIS is sometimes at odds with the Information Technology department regarding scope and responsibilities.

There are numerous "standing" reports prepared by the CIS group. The reports are usually delivered "raw" – without analysis, summaries or trending data sent with the report. Many of the reports are long standing and their utilization is unknown. CIS is not able to say which of the reports generated on a routine basis are actually used for management purposes. There is no formal process to request an ad hoc report and as such prioritization of completing report requests is on a "squeaky wheel" basis.

Medical Staff Performance Improvement

As part of the Gap Analysis, the A&M Survey Team evaluated the Medical Staff Services function at Parkland. Our review consisted of interviews with the Medical Staff Services Director and staff, a review of the Medical Staff Bylaws, Rules and Regulations, and review of samples of initial applications and reapplications for medical staff privileges for both Physicians

and Allied Health Professionals. While most elements of the Medical Staff Conditions of Participation (CoP) are met, the Hospital does not at this time have an effective Ongoing Professional Practice Evaluation (OPPE) program as part of its Medical Staff credentialing and peer review process. (Note: The OPPE action plan grid and timeline can be found in the Medical Staff section, 2.11, of the Corrective Action Plan.)

Applications/Credentialing

The general function of the Medical Staff Office meets the CMS Conditions of Participation requirements. The files are adequately secured; they are well organized and easy to access when retrieving specific information. The initial application process is appropriate. There is no pre-application process. The Hospital seldom grants temporary privileges in the initial application process. When temporary privileges are granted, all the required elements (e.g., State licensure, DEA number, National Practitioner Databank) are validated by primary sources and their use for credentialing is time-limited. Only in cases of immediate patient need are temporary privileges granted. The Hospital performs its own primary source verification for all new applicants. There are few delays for Medical Staff applicants and most applications are normally processed within the time period specified in the Medical Staff Bylaws.

There are delays, however, when processing some of the Allied Health Professional applications. This delay stems from a disconnect between the Human Resources Department and the Medical Staff Office during the hiring process. The Human Resource Department and Medical Staff Office do not coordinate effectively regarding new hires and the need for credentialing, therefore the application process is delayed.

Focused Professional Practice Evaluation (FPPE) is applied appropriately during initial applications and follow-up is timely for new applicants.

Requests for new privileges are processed through a formal channel. There is no utilization of practice information from other organizations or "grandfathering" involved in this process. Temporary privileges may be issued but only in cases of immediate patient need. Again, Focused Professional Practice Evaluation is applied appropriately and follow-up is timely for those Medical Staff applicants seeking new privileges.

The re-application process is appropriate from a processing point of view. There is, however, room for significant improvement in the quality assessment of Medical Staff members, including improvements in OPPE for all categories of staff.

OPPE is the ongoing assessment of an existing medical staff member's performance. Since January 2008 hospital medical staffs have been required to collect physician-specific data regarding six core competencies as defined by The Joint Commission, the American Board of Medical Specialties (ABMS) and the Accreditation Council for Graduate Medical Education (ACGME). These are the same six core competencies currently used to rate Medical Residents.

The six core competencies can be summarized as follows:

- **Patient Care and Procedural Skills:** Practitioners are expected to provide patient care that is compassionate, appropriate, and effective for the promotion of health, prevention of illness, treatment of disease, and care at the end of life.
- **Medical/Clinical Knowledge:** Practitioners are expected to demonstrate knowledge of established and evolving biomedical, clinical, and social sciences, and the application of their knowledge to patient care and the education of others.
- **Practice-Based Learning & Improvement:** Practitioners are expected to be able to use scientific evidence and methods to investigate, evaluate, and improve patient care practices.
- **Interpersonal & Communication Skills:** Practitioners are expected to demonstrate interpersonal and communication skills that enable them to establish and maintain professional relationships with patients, families, and other members of health care teams.
- **Professionalism:** Practitioners are expected to demonstrate behaviors that reflect a commitment to continuous professional development, ethical practice, an understanding and sensitivity to diversity and a responsible attitude toward their patients, their profession, and society. (The Joint Commission considers diversity to include race, culture, gender, religion, ethnic background, sexual preference, mental capacity, and physical disability.)
- **System-Based Practice:** Practitioners are expected to demonstrate both an understanding of the contexts and systems in which health care is provided, and the ability to apply this knowledge to improve and optimize health care.

We did not observe that Parkland's re-credentialing process is currently collecting and utilizing data to assess these six core competencies when conducting OPPE review as a part of the re-credentialing process. §482.22(b) TAG: A-0340 Standard: Composition of the Medical Staff; MS.08.01.03 (EP 1,2,3) – MS 06.01.05 (EP 3 ,8, 9, 10)

Information for OPPE can be acquired in a number of ways such as:

- Monitoring clinical practice patterns through process and outcome monitoring
- Periodic chart review
- Direct observation of procedures and patient care
- Simulation exercises
- Proctoring

- Discussion with others involved in the patient's care including consulting physicians, assistants at surgery, nursing, and administrative personnel

Some types of data that can be collected and used to perform OPPE can include:

- Morbidity and mortality data
- Operative and other clinical procedures and their outcomes
- Requests for tests and procedures
- Practitioner's use of consultants
- Length of stay (LOS)
- Transfusion practices
- Infection rates

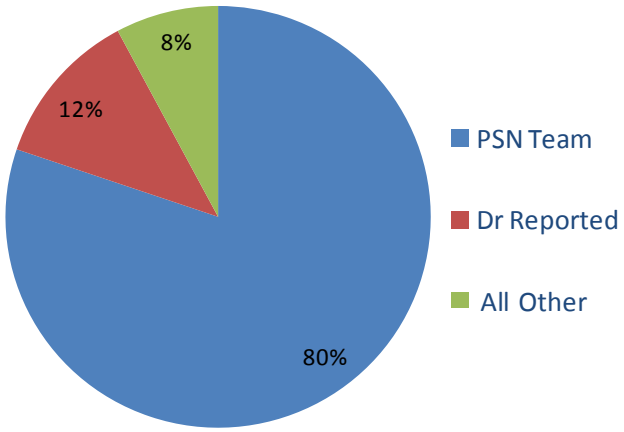
At present we did not find that this type of data was being collected on an organized basis for each Medical Staff member in order to effectively conduct OPPE. Until OPPE is improved and expanded, the organization will remain out of compliance with the CoP. 482.22(a)(1) TAG: 0340 Standard: Composition of the Medical Staff; *MS.08.01.03 (EP2, 3)*

Peer Review

The Medical Staff's Medical Executive Committee (MEC) has delegated to its Patient Care Review Committee (PCRC) the authority to conduct initial peer review at Parkland. Cases are referred to the PCRC by the Patient Safety Officer. The PCRC "scores" the cases and recommends actions to the MEC. If the Medical Staff member disagrees with a finding or recommendation of the PCRC and MEC, he/she may exercise his formal review rights, which includes a fair hearing before a panel of Medical Staff members.

Very few cases at Parkland appear to be referred to a formal peer review. Cases only go to peer review if they are scored a "3" or "0" after multiple pre-reviews. Currently, two employees in the Medical Staff Office process peer review background work for more than 1,000 physicians. The team does not have support to trend prior cases or assess if a case is an exception or a trend. Peer Review investigations, actions and reports are frequently viewed as "one-time" or "one-off" events. We did not see evidence of analysis of previous behaviors or trends when cases are brought to peer review, and were therefore unable to determine if the recommended actions were appropriate. Trending and assessment of prior cases and behavior patterns is critical to the success of the peer review process and should be implemented at Parkland. § 482.22(a)(1) TAG: A-0340Standard: Composition of the Medical Staff. MS.08.01.03 (EP 2, 3) – MS.06.01.05 (EP 3, 8, 9, 10).

Patient Safety Net (PSN) reported safety events are currently the primary source for identifying and funneling issues for peer review. PSN reports account for 85% of the referrals to peer review. The remaining 15% are direct referrals (e.g. daily rounding, observation). From the database reviewed by our surveyors, the two sources are not providing the number of charts for review that would normally be seen in an organization of this size and complexity. Peer review should be drawing many more cases for PCRC and MEC review from a wider funnel of all sources including PSNs, rounding, patient complaints, daily huddles, Epic/informatics, professional peer review databases, department meetings and Residents/GME. The Hospital needs more effective means to generate cases for peer review including new indicators that are "all comers." § 82.22(b) TAG: A-0347 Standard: Medical Staff Organization and Accountability; MS.08.01.03(EP 1,2,3) - MS 0.01.01 (EP 1,2)



The pre-peer review process is often subjective. Cases identified through PSN reports are initially reviewed by Patient Safety group and Patient Safety Officer for potential scoring (on a scale of 1 to 3) and for referral to the PCRC. Cases are reviewed by the Patient Safety Officer and sometimes by a reviewer physician in one of the departments and are scored on a scale of 1 to 3. At that point the Patient Safety group may close out cases, if it is scored at a "1" after the Patient Safety Officer reviews the case and determines that no further review is necessary. § 482.12(a)(6) TAG: A-0050 Standard: Medical Staff Organization and Accountability; MS.06.01.03 (EP 2).

Parkland's peer review process should include other key indicators that should trigger peer review including: medication reconciliation, which is an issue of significant concern to CMS and a requirement of the Parkland Bylaws; delays in care, disruptive behavior; and, adherence to infection control procedures.

Cases that are initially scored a "2" or "3" are sent to a designated physician reviewer for the appropriate department. The Department Chair or the Parkland Chief of Service appoints to the physician reviewer in the department. The department reviewer has two weeks to review the

case. Correspondence is sent back and forth through secure e-mail or through interoffice mail in a confidential envelope. The reviewer may speak with the physician involved during the review. If the reviewer scores the case as a 3 or 0 the case goes to the PCRC for concurrence. Cases can be scored a "0" by the reviewer, which is a score of "exemplary." It is very unusual to have an exemplary care category. Indeed, if a case is referred to peer review for inappropriate care, it seems unusual that the case would subsequently be scored exemplary.

Department peer reviews are not consistently integrated into the process. The indicators for deciding whether to refer a case to peer review are global and are not designed to obtain any objective data. They are written so the referrer must draw a conclusion in order to refer – i.e., "low birth weight due to inappropriate care" as opposed to birth weight less than 1000 grams. Or, "baby with Apgar less than 5 at 5 minutes due to inappropriate care." The indicator would be better written "Apgar less than 5 at 5 minutes." Each medical department should choose departmental specific "all comers" indicators, not global indicators by June 2012.

Reports containing all scored cases (2 and above) have only been going to the PCRC for the past six months. The peer review process does not use concurrent processes for accurate attribution. This is essential if the Board is to infer quality when re-appointing physicians to the Medical Staff.

In addition, as noted earlier, peer review investigations, actions and reports are mostly viewed as "one-time events" – there is no evidence of analysis of previous behaviors or trends to determine if the recommended actions are appropriate.

Much of the peer review process at Parkland is "siloed." Parkland currently views behavior and clinical practice issues separately from cases alleging bylaws, rules and regulations violations. The Hospital does not have an effective process to obtain referrals on rules violations except when reviewing charts. Department peer reviews are not consistently integrated into the process. While the Patient Safety group is currently building reports for surveillance so that all will be referred, those instances managed by HIM, are not initially seen by the Patient Safety Department, and the physician contact letter is being generated directly from HIM. In order to be compliant, it is important that Parkland have a single source for capturing and tracking all potential cases that should be subject to peer review. Department reviews should be closely tied to the larger peer review process. § 482.12.(a)(6) TAG: A-0050 Standard: Medical Staff Organization and Accountability; MS.06.01.03 (EP 2).

As noted above, the Hospital's continuing peer review process, "Ongoing Professional Practice Evaluation" (OPPE) is in its infancy. Similar to our observation above that Parkland's Medical Staff re-credentialing process does not effectively do OPPE, we found that the peer review process also does not effectively incorporate OPPE standards. For example, we did not observe Parkland's peer review process utilizing the six core competencies in OPPE review as we noted

above. §482.22(b) TAG: A-0340 Standard: Composition of the Medical Staff; MS.08.01.03(EP 1,2,3) - MS 06.01.05 (EP 3, 8, 9, 10)

The current peer review system at Parkland does not employ OPPE surveillance reports and techniques to identify practice trends for individual Medical Staff members. For example, the Medical Staff should be collecting trending data on all Medical Staff members to ascertain the quality and efficiency of their care. Measures such as: length of stay, re-admissions, surgical complications, surgical site infections and core measures should be utilized as a means to: 1) identify physicians who are outliers, in comparison to the rest of the Medical Staff or a department, and 2) help to better inform the peer review process to determine whether a particular case with a bad outcome is a "one off" outcome or whether it is indicative of a trend with that physician. Both the peer review process and the re-credentialing process should also consult external data bases such as those maintained by professional societies, governmental agencies or proprietary resources like the Vermont Oxford or Delta Group databases.

Further recommendations, monitoring methodologies and timelines can be found in the Medical Staff section of the Corrective Action Plan (Medical Staff, Section 2.11).

Summary of Findings – Review of Parkland's QAPI Program

Overall the QAPI program at Parkland is not as effective as it should be. It does not capture all quality related issues, events and initiatives and does not adequately prioritize and appropriately deploy resources as needed. The program does not engage in enough data analysis or trending studies or share information gleaned from that data across the organization. Data needs to be effectively utilized to measure not only performance improvement changes, but to monitor the ongoing efficacy of performance improvement efforts. The Parkland QAPI program often views quality through the lens of reported "adverse events." But too often adverse events are viewed as isolated or "one off" incidents as Parkland, rather than symptoms of a systemic problem within the organization.

At this time, Parkland's Quality Assessment and Performance Improvement plan does not meet the Medicare Conditions of Participation for hospital QAPI plan operation.

Parkland's QAPI Program - Recommendations

The Corrective Action Plan outlines several changes to the organization of Parkland's QAPI efforts. Key to the changes is the elevation of patient safety and patient rights issues to a Chief Patient Rights and Safety Officer (CPRSO), who will report directly to the Parkland Board of Managers and the Parkland CEO. (See Action Plan, Section 2.09, Patient Safety/Rights.)
As part of enhancing the focus on patient rights and safety at Parkland should reorganize its current safety and quality program to create a new Patient Rights and Safety Department. This department should be headed by a new senior executive at the Hospital: the Chief Patient Rights and Safety Officer (CPRSO).

To demonstrate the importance of patient rights and patient safety at Parkland, we recommend that this new officer become one of the senior officers in the Parkland system. Under this recommendation and reorganization, the CPRSO will report directly to the Parkland Board of Managers and the Parkland CEO. The following quality and safety functions at Parkland would be reorganized to report directly to the CPRSO:

- Patient Safety
- Patient Safety Investigations
- Root Cause Analysis (RCA)
- Patient Safety Incident Reporting
- PSN Database Maintenance and Reporting
- State, Federal and Joint Commission Reporting
- "Daily Rounding" Function
- Infection Prevention and Control
- Patient Relations (Patient complaints and grievances, which currently reports to Nursing)

A&M will work with the Parkland's BOM and CEO to devise a job description for the new CPRSO. At a minimum, the CPRSO should have a healthcare background, preferably with direct clinical experience, experience in quality analytics, experience in conducting safety and quality of care investigations and experience in managing a large staff and department. The successful candidate should also have a record of promoting patient safety and patient rights in previous work experiences. After a job description has been completed, Parkland should conduct a national search for the CPRSO. Given the length of time necessary to conduct a national search, the Parkland BOM should designate an Interim CSPRO. The Interim CSPRO should not be a candidate for the permanent position. Additionally, while candidates from Parkland or UTSW should not be completely ruled out, Parkland would greatly benefit from a candidate who brings significant and fresh perspective from outside of the Parkland or UTSW systems and does not have any existing relationships or loyalties with any other members of the Parkland or UTSW organizations.

Establishment of the CPRSO and reorganization of all units and departments into the CSPRO will also require new job descriptions for all employees and managers, supervisors and department heads in units and divisions now reporting to the CPRSO. Key employees within the new department should all have clinical or caregiver experience as well as excellent investigative and analytical skills.

The establishment of a new CPRSO department should also entail a review and rewrite of all patient rights and safety related policies and procedures and training and education materials to ensure that all Parkland policies and procedures and educational materials on patient rights and safety reflect and incorporate all current requirements of Medicare CoP, The Joint Commission standards, and all requirements of the State of Texas.

By instituting this new Patient Rights and Safety function, Parkland will have to reorganize and redesign the current Quality Department and the centralized Quality Assessment/Performance Improvement (QAPI) functions. Following the establishment of the CPRSO and Department, the Parkland Quality Department should continue to focus upon: QAPI coordination, quality consulting to Hospital departments and units, and informatics/analytics. Functions remaining in the Quality Department should include:

- Clinical Data Management
- Performance Improvement
- Rapid Cycle Improvement
- "Continual Readiness in CMS, State, and Joint Commission Surveys

As elsewhere recommended in the Corrective Action Plan (Section 2.05), the Utilization Review/Utilization Management function should be combined into the Hospital's Case Management/Discharge Planning function.

The Quality Department should also take the lead in providing quality and utilization data to the Medical Staff Office so that the Medical Staff can implement a compliant Ongoing Professional Practice Evaluation (OPPE) process.

Additionally, the Quality Department should continue to be responsible for oversight of all departmental/unit-level QAPI plans and for rolling up all department/unit-level QAPI data and indicators into the Hospital-wide QAPI plan.

Although the creation of a Patient Rights and Patient Safety Department and CPRSO will divide some of current tasks of the Quality Department, both the Quality Department and the Patient Rights and Safety Department will need to continue to work closely and collaboratively on efforts to improve care at Parkland and guarantee all patients a safe care experience.

Work Plan and Timetable for Corrective Action to Parkland QAPI Plan

Task	Monitoring	Timeline
Revise QAPI plan • Include CMS elements • Prioritize efforts and resources • Customize indicators to reflect specific patient populations in each department • Define methodology to capture and analyze data • Define formal process for reporting to Quality of Care Committee (QCC) and the BOM Quality Committee. • Identify a regular reporting schedule for each department	QCC should review all PI projects house-wide	Weeks 1 – 4
Approval of QAPI plan by the QCC and BOM Quality Committee.		Week 4
Capture and analyze baseline data from initial tracers for survey readiness.		Weeks 1 – 3
Develop and implement corrective action plan for survey readiness		Weeks 1 – 6
Performance Improvement group should implement rounding as a method to collect data for adverse patient events		Weeks 2, Ongoing
Performance Improvement group to develop a list of resources from which to pull adverse patient events		Weeks 2 – 4
Develop methodology to trend, analyze and report adverse patient events	Report to Senior Management and Quality Committee of BOM	Week 2, Ongoing
Work with A&M to improve RCA process		TBD

Task	Monitoring	Timeline
Develop a master report of all RCAs conducted. Include incident date, date of RCA commencement, date of RCA conclusion, general results and actions taken.	Monthly report to Quality Committee of BOM	Week 1 – ongoing
Review standing reports generated by CIS and meet with end users/management to determine relevance and meaningfulness. Discontinue generation of reporting that does not add value to end user/management.		Week 1 – Week 4
Establish a schedule for CIS with due dates of all necessary reporting		Week 4
Patient Safety to revise and standardize scoring system used to refer cases to peer review	Approval by MEC, PCRC	Week 1 – Week 4.